

VCU 02-14
Amendment dated 10/21/2011

10/565,852
Reply to office action mailed 06/21/2011

02940323aa

REMARKS

Claims 1-14 are currently pending in the application. By this amendment, claims 1, 4, 7, 8, 11 and 14 are amended for the Examiner's consideration. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

The Examiner's consideration in an interview on October 19, 2011, is acknowledged with appreciation. The Examiner reviewed the attached Agenda prior to the interview and indicated in the interview that a) the "attenuation" language of the amendment was sufficient to overcome the § 112 rejection and b) in view of the first point in the Agenda the Henriquez/Bridger ground of rejection would be withdrawn. The Examiner also indicated that a further search would be done of non-patent literature regarding the eyeball resonance range. **Applicant requested continuation of the interview prior to issuance of a further office action, and offered to provide a suitable Article 132 Declaration if that would be a helpful in adding to the record on any factual points desired by the Examiner.**

Although agreement has been reached regarding the sufficiency of the "attenuation" language to overcome the Examiner's rejection of claims 1-14 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, the following additional remarks are provided for completeness of the record. The Examiner asserts that "it is unclear how one will be able to apply intracranial pressure directly to the eyeball of a patient **without interference from the skull of the patient**" (emphasis supplied). What the highlighted language refers to is the fact that the measurement of intracranial pressure can be accomplished **without interference from the skull of the patient** only through the eye or the ear, and the eye measurement is the least invasive (see page 2, lines 8-23). While it is true, as the Examiner points out, that intracranial pressure necessarily involves the skull (whose rigidity relative to expansion of brain tissue and fluids cooperates to produce "the

pressure applied to the eyeball”), it is nonetheless also true that the eye is like a window for seeing inside a room “without interference” from the walls of the room.

In the analogy of a room with a window, the inside of the room cannot be “seen” at all (at visual wavelengths) by “looking” through the wall. On the other hand, sound signals from within the room that could be heard more clearly from outside the room at a window would be attenuated if heard through a wall without a window. The variation of attenuation effects with frequency may be understood by another analogy, by considering the behavior of cats. While cats can see, they are particularly noted for their acute hearing, which extends into the ultrasonic range. It has been observed that cats prefer to “observe” their surroundings through a window which is open rather than closed. This is because while their eyes can “see” through a closed glass window, the glass attenuates the sound and cats prefer to “observe” with their ultrasonic ears, without the attenuation of sound waves provided by the glass in the window. A similar attenuation would be provided by the bone in the eye socket, which is why the sensor is not to come in contact with the eye socket (page 10, lines 1-5).

The claim language has therefore been amended to replace “interference from” with “attenuation by” and to make clear that this refers to the measurement of the intracranial pressure and the signal damping without having to go through the skull itself.

Although agreement has been reached overcoming the combination of the Henriquez and Bridger references, the following additional remarks are provided for completeness of the record. The Examiner had maintained rejection of claims 1-6 and 8-13 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,129,403 to Henriquez et al. (“Henriquez”) in view of U.S. Patent No. 5,919,144 to Bridger et al. (“Bridger”). The present invention is based upon the use of ultrasonic resonant frequencies of the eyeball. There is no disclosure of using a resonant frequency of the eyeball in either Bridger or Henriquez. While Henriquez discloses

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use of the eye, there is no discussion at all of resonance. While Bridger discusses resonance, it is all directed toward vascular beds in the brain. The eye has two distinct aspects. In one aspect, as disclosed by Henriquez, the eye serves as a window on the brain. In a second aspect, the eye has a resonant frequency. One skilled in the art has nothing in the combination of Bridger and Henriquez to warrant concluding that the eye has a resonant frequency that could be used as claimed.

The amended claim language clarifies the scope of the eyeball resonance limitation. The observation of the inventors is that the particular resonance frequency of the eyeball for a particular patient varies “across a range” of patients (see page 15, line 3). Therefore, the sweep generator applies acoustic signals across a “predetermined range covering a corresponding range of resonant frequencies across a range of patients.” Dependent claims 4 and 11 have been amended to provide a specific definition of such a predetermined range, namely, the range of 30-50 kHz (as indicated at page 8, line 31).

Further, claims 7 and 14 have been amended to clarify their relationship to the claims from which they depend. Claims 1 and 8, respectively, provide a determination of ICP from an analysis of the degree of damping at the eyeball resonant frequency of the patient, the determination being made from the output of the acoustic eye patch. Claims 7 and 14 use measurements from the acoustic eye patch to provide a further measure of ICP. This further measure is in addition to the measure provided by the damping analysis, and relies upon pressure applied via the acoustic eye patch until retinal artery pulsations disappear (page 15, lines 8-21). The reference in claims 7 and 14 to the “predetermined range” is confusing and misleading, and has been deleted.

The foregoing amendments pertain to the the Examiner’s rejection of claims 7 and 14 under 35 U.S.C. §103(a) as being unpatentable over Henriquez in view of Bridger and further in view of U.S. Patent No. 3,903,871 to Chisum et al. (“Chisum”). Having clarified the dependency of claims 7 and 14 from claims 1 and

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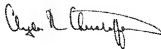
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8, respectively, it is clear that amended claims 7 and 14 overcome this ground of rejection on the basis of the Examiner's withdrawal of the Henriquez/Bridger combination. In addition, as to the Chisum reference, which is a long expired ophthalmodynamometer patent, Chisum does not disclose the application of pressure via an acoustic eye patch, where an analyzer is used to detect cessation of retinal artery pulsations. Instead, the Chisum reference discloses pressure applied by a bladder against the eyeball, where there is a correlation between the measured bladder pressure and the retinal artery pressure. Chisum fails to disclose or suggest a measurement at the point when the bladder pressure causes arterial pulsations to cease. Consequently, Chisum fails as a reference.

In view of the foregoing, it is requested that the application be reconsidered, that claims 1-14 be allowed, and that the application be passed to issue.

If a further extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Sincerely,



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AGENDA FOR INTERVIEW
WEDNESDAY, OCTOBER 19, 2011, 11:00 AM

- I. Whether the Bridger disclosure supports extension of the Bridger technique to other resonant structures besides vascular beds (see col 4, lines 23-47).

Discussion: the present invention is based upon the use of ultrasonic resonant frequencies of the eyeball. There is no disclosure of using a resonant frequency of the eyeball in either Bridger or Henriquez. While Henriquez discloses use of the eye, there is no discussion at all of resonance. While Bridger discusses resonance, it is all directed toward vascular beds.

Argument: the eye has two distinct aspects. In one aspect, as disclosed by Henriquez, the eye serves as a window on the brain. In a second aspect, the eye has a resonant frequency. One skilled in the art has nothing in the combination of Bridger and Henriquez to use the eye's resonant frequency.

- II. Whether the cited prior art discloses or suggests a correlation between intra-cranial pressure (ICP) and the claimed degree of damping at the resonant frequency of the eyeball.

Argument: Based on Bridger and Henriquez, one skilled in the art would have to perform "undue experimentation" to identify a correlation between ICP and damping at the resonant frequency of the eyeball.

Note: the "predetermined range" in the claims is responsive to the experimental observation that variation in the structure of the eyeball from one human patient to another means that the resonant frequency varies, nominally between 33-43 kHz (page 8, lines 30-32), so that the desired procedure is to scan around that range to be sure that the resonant frequency for any particular patient is found (page 9, lines 1-7).